



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|----------------------|---------------------|------------------|
| 10/658,261 | 09/10/2003 | Adam L. Cohen | 06530.0307 | 4026 |
| 22852 | 7590 | 12/28/2007 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | LLOYD, EMILY M | |
| ART UNIT | PAPER NUMBER | | 3736 | |
| MAIL DATE | DELIVERY MODE | | 12/28/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

H

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/658,261 | COHEN ET AL. |
| | Examiner | Art Unit |
| | Emily M. Lloyd | 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 September 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12, 14-25, 27 and 78-87 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12, 14-25, 27 and 78-87 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. This office action is in response to the amendment filed 24 September 2007. The Examiner acknowledges the amendment to claims 1, 14, and 25, the cancellation of claims 13, 26, and 28-77, and the addition of claims 78-87; the substitute specification; and the replacement drawing sheet for Figures 10A-10C. Currently, claims 1-12, 14-25, 27, and 78-87 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14-20, 22-25, and 83-85 are rejected under 35 U.S.C. 102(b) as being anticipated by International Publication Number WO 01/30242 (Paternuosto).

Regarding claim 14, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4), wherein the open top and the open bottom are aligned with a longitudinal axis of the cavity (Figure 7); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through

the open top (5th paragraph of page 4); wherein a portion of the elongate container adjacent the open bottom has an hourglass shape configured to prevent the plurality of tissue samples from exiting the container via the open bottom (the walls of container element 22 immediately above and below hole 18 form an hour-glass shape, Figure 7, and this is adjacent the open bottom; for biopsy samples that fill the biopsy jaws the pieces would remain in the jaws due to the constriction of the hourglass shape).

Regarding claim 15, Paternuosto discloses the device of claim 14, wherein the cutting portion (front rim 12 Figures 5 and 7) selectively couples to the open top of the elongate container (Figure 7) and defines a through hole (hole 18 Figures 5 and 7) in flow communication with the open top, the cavity, and the open bottom (Figure 7).

Regarding claim 16, Paternuosto discloses the device of claim 14, wherein the cutting portion comprises an upper jaw (half-shell 10A Figure 6) and a lower jaw (half-shell 10B Figure 7) configured to cut tissue when the upper jaw mates with the lower jaw (last paragraph of page 5 and Figures 2 and 3).

Regarding claim 17, Paternuosto discloses the device of claim 16, wherein the lower jaw (half-shell 10B Figure 7) includes a through hole (hole 18 Figure 7), and wherein the lower jaw is coupled to the open top of the elongate container such that the through hole is in flow communication with the open top, the cavity, and the open bottom (adhesive 30 Figure 7 and the 4th paragraph of page 5).

Regarding claim 18, Paternuosto discloses the device of claim 16, wherein the upper jaw includes a protrusion (central portion 26 Figure 6) configured to push the plurality of tissue samples into the cavity (last paragraph of page 5).

Regarding claim 19, Paternuosto discloses the device of claim 18, wherein the protrusion extends adjacent an edge of the upper jaw (central portion 26 is adjacent to the edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 20, Paternuosto discloses the device of claim 16, wherein the upper jaw is configured to restrict the plurality of tissue samples from adhering to the upper jaw (central portion 26 Figure 6 and last paragraph of page 5).

Regarding claim 22, Paternuosto discloses the device of claim 16, wherein at least one of the upper jaw and the lower jaw has a support portion (support portion 16 Figure 2 and 3, see also the last paragraph of page 5) configured to allow the upper jaw and the lower jaw to rotate with respect to each other (last paragraph of page 3).

Regarding claim 23, Paternuosto discloses the device of claim 14, wherein the elongate container includes an angled base wall adjacent the open top (the wall of container element 22 adjacent base wall 14 is angled and adjacent the open top).

Regarding claim 24, Paternuosto discloses the device of claim 14, wherein the elongate container is configured to restrict the plurality of tissue samples from adhering to an inner wall of the elongated container (openings 24 Figure 7).

Regarding claim 25, Paternuosto discloses the device of claim 14, wherein the elongated container includes at least one hole in a side wall of the elongate container (openings 24 on the sides of container element 22, Figure 7).

Regarding claim 83, Paternuosto discloses the device of claim 14, wherein the portion of the elongate container adjacent to the open bottom is configured to mate with a flushing device (opening 24 Figure 7).

Regarding claim 84, Paternuosto discloses the device of claim 19, wherein the protrusion is adjacent to the outer edge of the upper jaw (central portion 26 is adjacent to the outer edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 85, Paternuosto discloses the device of claim 84, wherein the protrusion is oval shaped (central portion 26 would be circular based on Figures 4 and 6; a circle is a particular case of an ellipse (a type of oval) where the major axis is equal in length to the minor axis).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7, 9-12, 27, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto.

Regarding claim 1, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through the open top (5th paragraph of page 4). Paternuosto also discloses that a portion of the elongate container adjacent the open bottom is configured to prevent the plurality of tissue samples from exiting the container via the open bottom (the portion of the container element 22 that surrounds the bottom opening 24 would function to keep the samples in the container); a portion of the elongate container adjacent the open bottom having an hourglass shape defining a restriction to prevent the plurality of tissue samples from passing through the restriction and exiting the container via the open bottom (the walls of container element 22 immediately above and below hole 18 form an hour-glass shape, Figure 7, and this is

adjacent the open bottom; for biopsy samples that fill the biopsy jaws the pieces would remain in the jaws due to the constriction of the hourglass shape). Paternuosto does not disclose that the restriction defined by the hour-glass shape is smaller than the open bottom. However, it would have been obvious to one of ordinary skill of the art at the time of the invention that such a change in size/proportion could be made that would perform the same function as the invention of Paternuosto because this size/proportion change would still allow the fluids to flow through the container (as described regarding openings 24 on the 6th paragraph of page 4) without losing the biopsy samples that the device is designed to cut and retain for testing (3rd through 5th paragraphs of page 2) and because such changes in size/proportion are obvious (MPEP 2144.04 IV A).

Regarding claim 2, Paternuosto discloses the device of claim 1, wherein the cutting portion (front rim 12 Figures 5 and 7) selectively couples to the open top of the elongate container (Figure 7) and defines a through hole (hole 18 Figures 5 and 7) in flow communication with the open top, the cavity, and the open bottom (Figure 7).

Regarding claim 3, Paternuosto discloses the device of claim 1, wherein the cutting portion comprises an upper jaw (half-shell 10A Figure 6) and a lower jaw (half-shell 10B Figure 7) configured to cut tissue when the upper jaw mates with the lower jaw (last paragraph of page 5 and Figures 2 and 3).

Regarding claim 4, Paternuosto discloses the device of claim 3, wherein the lower jaw (half-shell 10B Figure 7) includes a through hole (hole 18 Figure 7) in flow communication with the open top and the open bottom, and wherein the lower jaw is coupled to the open top of the elongate container such that the through hole is in flow

communication with the open top, the cavity, and the open bottom (adhesive 30 Figure 7 and the 4th paragraph of page 5).

Regarding claim 5, Paternuosto discloses the device of claim 3, wherein the upper jaw includes a protrusion (central portion 26 Figure 6) configured to push the plurality of tissue samples into the cavity (last paragraph of page 5).

Regarding claim 6, Paternuosto discloses the device of claim 5, wherein the protrusion extends around an edge of the upper jaw (central portion 26 is around the inner edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 7, Paternuosto discloses the device of claim 3, wherein the upper jaw is configured to restrict the plurality of tissue samples from adhering to the upper jaw (central portion 26 Figure 6 and last paragraph of page 5).

Regarding claim 9, Paternuosto discloses the device of claim 3, wherein at least one of the upper jaw and the lower jaw has a support portion (support portion 16 Figure 2 and 3, see also the last paragraph of page 5) configured to allow the upper jaw and the lower jaw to rotate with respect to each other (last paragraph of page 3).

Regarding claim 10, Paternuosto discloses the device of claim 1, wherein the elongate container includes an angled base wall adjacent the open top (the wall of container element 22 adjacent base wall 14 is angled and adjacent the open top).

Regarding claim 11, Paternuosto discloses the device of claim 1, wherein the elongate container is configured to restrict the plurality of tissue samples from adhering to an inner wall of the elongated container (openings 24 Figure 7).

Regarding claim 12, Paternuosto discloses the device of claim 1, wherein the elongated container includes at least one hole on a side wall (openings 24 on the sides of container element 22, Figure 7).

Regarding claim 27, Paternuosto discloses the device of claim 14 (see the 102(b) rejection above). Paternuosto does not disclose that the portion of the elongate container adjacent the open bottom has a restriction that is smaller than the open bottom. However, it would have been obvious to one of ordinary skill of the art at the time of the invention that such a change in size/proportion could be made that would perform the same function as the invention of Paternuosto because this size/proportion change would still allow the fluids to flow through the container (as described regarding openings 24 on the 6th paragraph of page 4) without losing the biopsy samples that the device is designed to cut and retain for testing (3rd through 5th paragraphs of page 2) and because such changes in size/proportion are obvious (MPEP 2144.04 IV A).

Regarding claim 78, Paternuosto discloses the device of claim 1, wherein the portion of the elongate container adjacent to the open bottom is configured to mate with a flushing device (opening 24 Figure 7).

Regarding claim 79, Paternuosto discloses the device of claim 6, wherein the protrusion is adjacent to the outer edge of the upper jaw (central portion 26 is adjacent to the outer edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 80, Paternuosto discloses the device of claim 79, wherein the protrusion is oval shaped (central portion 26 would be circular based on Figures 4 and

6; a circle is a particular case of an ellipse (a type of oval) where the major axis is equal in length to the minor axis).

8. Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto as applied to claims 1-7, 9-12, 14-20, 22-25, and 27 above, and further in view of United States Patent 5662671 (Barbut et al.).

Regarding claims 8 and 21, Paternuosto discloses the devices of claims 3 and 16 in the 103(a) and 102(b) rejections above, respectively. Paternuosto does not disclose that the upper jaw defines a plurality of holes. Barbut et al. teaches the use of the upper jaw defining a plurality of holes (perforations 282 and 285 in clam shells 280 and 283, Figure 15A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such an upper jaw defining a plurality of holes as taught by Barbut et al. to provide for the movement of fluid and air while retaining the biopsy sample in the device in the invention of Paternuosto because this would provide an additional means of discharging air and liquids, which would better help the biopsy samples to move into the container element (Paternuosto 6th paragraph page 4) and permit blood flow out of the device (Barbut et al. Column 17 lines 45-48).

9. Claims 81-82 and 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto as applied to claims 1-7, 9-12, 14-20, 22-25, 27, 78-80, and 83-85 above, and further in view of United States Patent 2778357 (Leibinger et al.).

Regarding claims 81 and 86, Paternuosto discloses the devices of claims 79 and 84 in the 103(a) and 102(b) rejections above, respectively. Paternuosto does not disclose that the protrusion surrounds an inner non-protruding portion. Leibinger et al.

teaches the use of a protrusion surrounding an inner non-protruding portion (jaw member 13b Figure 2 of "male shape" Column 2 lines 21-22 that "penetrates ... into the jaw member 13a" Column 2 lines 20-21; "open construction" Column 2 line 24 indicates a non-protruding portion 13c Figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a protrusion surrounding an inner non-protruding portion as taught by Leibinger et al. to provide for the movement of fluid and air while retaining the biopsy sample in the device in the invention of Paternuosto because this would provide an additional means of discharging air and liquids, which would better help the biopsy samples to move into the container element (Paternuosto 6th paragraph page 4).

Regarding claims 82 and 87, Paternuosto as modified by Leibinger et al. teach the devices of claims 81 and 86, wherein the inner non-protruding portion defines at least one ventilating hole (Leibing et al. "open construction" Column 2 line 24, 13c Figure 2).

Response to Arguments

10. Applicant's arguments filed 24 September 2007 have been fully considered but they are not persuasive.
11. In response to applicant's argument that Paternuosto does not disclose an hour-glass shape configured to prevent the plurality of samples from exiting the container via the open bottom, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. In response to applicant's argument that Paternuosto does not use its restricted neck/hourglass shape to retain biopsy samples, in the case of biopsy samples that fill the biopsy cups the neck would function in this manner. Additionally, the structure of Paternuosto meets the structural limitations claimed.

13. In response to applicant's argument that Paternuosto's shape functions to allow the discharge of organic liquids while retaining the plurality of tissue samples and therefore it is unclear why one of ordinary skill in the art would be motivated to change its shape, the Examiner first notes that this motivation has been changed in light of applicant's amendments. Further, substitution of equally effective shapes, sizes, etc are known in the art as equivalents and such motivation is detailed in the MPEP (MPEP 2144.04 I-V).

14. In response to applicant's argument that Paternuosto's invention is intended to hold many samples and a change in shape would reduce the number of samples that can be held, the Examiner first notes that this motivation has been changed in light of applicant's amendments. Further, there is no evidence that one would fill cavity 20 Figure 7 of Paternuosto completely. Additionally, in the case of biopsy samples that fill the biopsy cups the half-shell 10b Figure 7 would fill and the reduction in size of cavity 20 would not be a concern.

15. In response to applicant's argument that new claims 79-80 and 84-85 are not disclosed by Paternuosto, the Examiner disagrees. See the 103(a) and 102(b) rejections of claims 79-80 and 84-85, respectively, above.

16. In response to applicant's argument that new claims 81-82 and 86-87 are not disclosed by Paternuosto, the Examiner agrees. However, the claims have been rejected under 35 U.S.C. 103(a) by Paternuosto as modified by Leibinger et al. above.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-

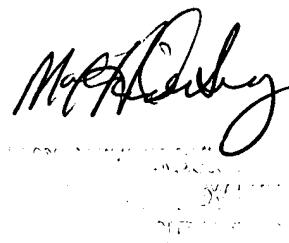
2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/



A handwritten signature in black ink, appearing to read "Max Hindenburg". Below the signature, there is a small, faint printed area that appears to be a stamp or a series of numbers.